Preliminary Data of BellaSeno's Clinical Trial on Scaffold-Guided Breast Regeneration Presented at the 93rd Annual Plastic Surgery Meeting in San Diego, CA

- *Performance: Statistically significant superiority over fat grafting, with breast volume retention twice as high*
- *Safety: BellaSeno's scaffolds are safe and improve patient satisfaction and well-being*

Leipzig, Germany, October 9, 2024 - BellaSeno GmbH, an ISO 13485 certified tissue regeneration company developing resorbable scaffolds using additive manufacturing technologies, today announced that new clinical data from the first interim report of its ongoing study evaluating the use of BellaSeno's 3D-printed resorbable breast scaffolds (ClinicalTrials.gov ID NCT05437757) were presented at the 93rd Annual Plastic Surgery Meeting in San Diego, CA, USA (Sept. 26 - 29, 2024).

The study is headed by Principal Investigator Professor Owen Ung, Professor of Surgery, University of Queensland and Program lead for the Breast Reconstruction at the Herston Biofabrication Institute Brisbane Australia) Preliminary results were presented by PhD student and plastic surgeon Matthew Cheng while Prof. Dr. Anand Deva, Professor at Macquarie University Health Sciences Centre, presented the benefits of the novel technology in terms of safety and performance in the field of reconstructive and aesthetic breast surgery during the panel "Safety First: A Deep Dive into Registries, BIA-ALCL and Regulatory Realities".

The open-label, single-arm study, sponsored by BellaSeno's Australian subsidiary, BellaSeno Pty Ltd, evaluated the safety and performance of medical grade polycaprolactone (mPCL) breast scaffolds in women undergoing breast implant revision surgery. Patients underwent capsulectomy and removal of the silicone implants which were then replaced by a prepectoral mPCL breast scaffold filled with approx. 50% volume of autologous fat graft. Key endpoints were safety, performance (volume sustenance) and patient satisfaction / quality of life.

In the study, scaffolds were successfully implanted in all 19 patients enrolled. Thirteen patients have completed a 12-month follow-up and 2 patients a 24-month follow-up with no explantations, infections, necrosis, and none of the complications typically associated with silicone implants (e.g., capsular contraction).

The analysis of the data of the first 10 patients one year after surgery demonstrated statistically significant higher breast volume sustenance achieved by BellaSeno´s mPCL breast scaffold in conjunction with autologous fat grafting (80%) compared to patients who received only autologous fat grafting for re-augmentation of the breast during silicone implant revision surgery (60% volume sustenance, literature control). MRI imaging also

showed good soft tissue retention at 12 months post-surgery. Patient-reported outcomes indicated robust improvements in breast satisfaction, sexual well-being and psychosocial well-being compared to pre-operative baseline.

"We are excited by these results, which suggest that protected autologous reconstruction (PAR) using fully resorbable mPCL breast scaffolds to protect the fat graft by shielding it from the forces of surrounding tissue pressure could become a groundbreaking option for women seeking breast implant revision, augmentation or reconstruction," said Professor Owen Ung, Principal Investigator, Professor of Surgery, University of Queensland and Program lead for the Breast Reconstruction at the Herston Biofabrication Institute Brisbane Australia. "Our research shows that this approach can potentially provide predictable, natural, long-lasting results while eliminating the risks associated with permanent implants. We are looking forward to expanding this study into an international multi-centre trial, which will allow us to bring this transformative technology to benefit many more patients worldwide."

"Traditionally, breast augmentation and reconstruction have relied on silicone implants, which can lead to complications such as capsular contracture, implant rupture and, in rare cases, the development of breast implant-associated anaplastic large cell lymphoma," said Professor Anand Deva.

"Our resorbable scaffold combined with an autologous fat graft offers a new solution. Over time, these scaffolds gradually resorb and allow the body to reconstruct natural tissue, resulting in a controlled, autologous regeneration process. This potentially results in a safer, more natural option which can be used in a broad range of indications, from aesthetic surgery for breast augmentation to breast cancer following mastectomy or lumpectomy," said PD Dr. med. Tobias Grossner, Chief Medical Officer of BellaSeno.

This clinical trial builds on extensive preclinical research and an ongoing successful first-in-human study for pectus excavatum correction using the same scaffold technology which has received EU Market Authorization in 2023. The study team will continue to monitor patients to determine the long-term safety and performance of the mPCL scaffolds, with final results expected in the coming years.

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About BellaSeno

BellaSeno GmbH was founded in 2015 and is headquartered on the BioCity campus in Leipzig, Germany, with a subsidiary in Brisbane, Australia. The Company is developing novel resorbable soft tissue and bone reconstruction implants made by additive manufacturing (3D-printing) under EU MDR certification. The Company has received substantial financial support from private investors as well as from the Saxony Development Bank (SAB), the European Fund for Regional Development (EFRE), Germany´s Federal Ministry of Education and Research (BMBF) and the Australian government. The Company has been co-funded from tax resources based on the budget adopted by the members of Saxony State Parliament.

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